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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/546,005

08/18/2005

Ingemar Starke

056291-5211

8620

9629 7590 04/16/2007
MORGAN LEWIS & BOCKIUS LLP
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EXAMINER

O DELL, DAVID K

ART UNIT

PAPER NUMBER

1609

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

04/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/546,005

Applicant(s)

STARKE ET AL.

Examiner

David K. O'Dell, Ph.D.

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-25 are pending in the current application.

Priority

2. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 371, **a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet.** For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, **the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application.** See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A

benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, Claims 1-12, 14, 15, & 18 drawn to compounds and compositions possessing a benzothiazepine core where in applicant's Markush structure of Formula I M^1 is CH_2 , M^2 is NR^{24} , R^1 and R^2 are H or lower alkyl, $R^3=R^4=R^7=R^9=R^8=R^{14}=R^{15}=R^{17}=R^{24}=H$, R^6 is H or SMe, R^5 is IA, Z is O, R^{10} is cyclohexyl or phenyl, $n=1$, $m=0$, R^{13} is IB $p=1$, $q=0$, R^{16} is OH, and $r=5$ shown as structure I in Figure 1.

Group II, Claims 1-12, 14, 15, & 18 drawn to compounds and compositions possessing a benzothiepine core where in applicant's Markush structure of Formula I M^1 is CH_2 , M^2 is $CR^{22}R^{23}$, $R^{22}=OH$, R^1 and R^2 are H or lower alkyl, $R^3=R^4=R^5=R^7=R^9=R^8=R^{14}=R^{15}=R^{17}=R^{23}=H$, R^6 is IA, Z is S, R^{10} is cyclohexyl or phenyl, $n=1$, $m=0$, R^{13} is IB $p=1$, $q=0$, R^{16} is OH, and $r=5$ shown as structure II in Figure 1.

Group III, Claims 1-9, 14, 15, & 18 drawn to compounds and compositions possessing a polypyridine core where in applicant's Markush structure of Formula I M^1 is CH_2 , M^2 is NR^{24} , R^1 and R^2 are H or lower alkyl, $R^3=R^4=R^7=H$, R^6 is H, R^5 is IA, Z is S, $n=2$, R^8 is heterocyclyl and the heterocyclyl is 4-pyridyl, $m=2$, R^{10} and R^{11} are heterocyclyl and the heterocyclyl is 4-pyridyl, R^{13} is IB $p=3$, R^{15} is heterocyclyl and the heterocyclyl is 4-pyridyl, q is 1, X is $S(O)_n$ (where this particular n is also 2), R^{16} is heterocyclyl and the heterocyclyl is 4-pyridyl, $r=3$, R^{17} is IC, R^{19} is heterocyclyl and the heterocyclyl is 4-pyridyl, $z=3$, R^{20} is heterocyclyl- $(C_{1-10}alkylene)R^{54}(C_{1-10}alkylene)_h$, and the heterocyclyl is 3-pyridyl the $C_{1-10}alkylene$ is a C_{10} skipped diene, R^{54} is SO_2 and 3-pyridyl of the heterocyclyl of R^{20} is substituted with R^{57} in the 2 position R^{57} is heterocyclyl- $(C_{1-10}alkylene)R^{60}(C_{1-10}alkylene)_h$, and the heterocyclyl is 2-pyridyl the $C_{1-10}alkylene$ is a C_{10} skipped diene, R^{60} is SO_2 which is shown as structure III in Figure 1.

Groups IV-VI, Claim 13 drawn to processes for the preparation of compounds limited in scope to one of the groups I-III.

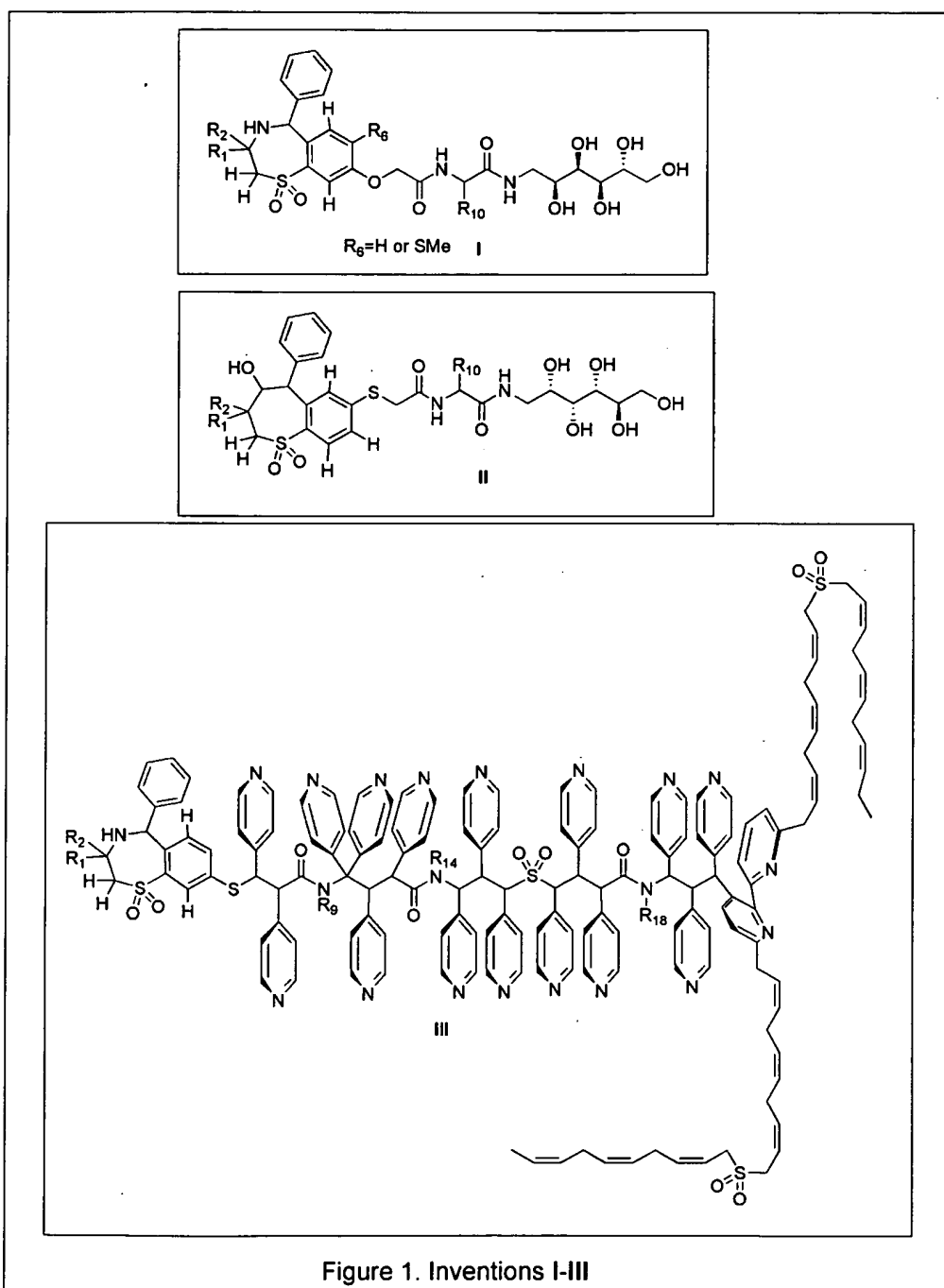
Groups VII-IX, Claims 16-17 drawn to methods of treatment with compounds of groups I-III limited in scope to one of the groups I-III.

Groups X-XII Claims 19, 22-23 drawn to combination compositions with compounds of groups I-III and statin drugs limited in scope to one of the groups I-III.

Groups XIII-XV Claims 20 and 21 drawn to combination compositions with compounds of groups I-III and bile acid binders etc. limited in scope to one of the groups I-III.

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Groups XVI-XVIII Claims 24-25 drawn to combination compositions with compounds of groups I-III and PPAR- γ or PPAR- α limited in scope to one of the groups I-III.



The inventions listed as Groups I- XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

(f) "Markush practice" The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

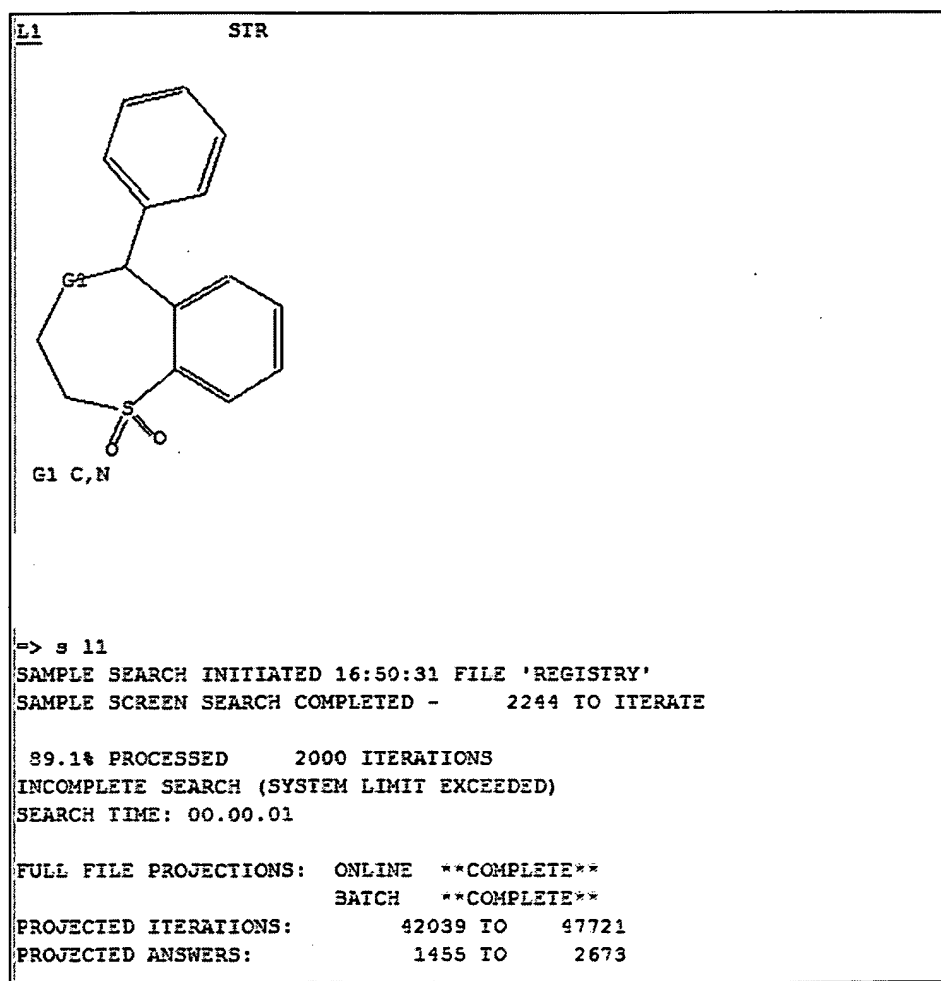
(B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art,

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and the common structure is essential to the common property or activity. The different variables M1, M2, Z, m, n, o, p, q, r and r R1-R67, etc. result in so many permutations giving both heterocyclic and non-hetero rings, different bonds between atoms, resulting in compounds that have achieved a different status in the art, and thus are drawn to an improper Markush group on the grounds of lack of a common nucleus. Thus lack of unity is apparent.

A preliminary search of a selected core gave numerous iterations, see below:



Thus it is clear that applicant's compound core is not applicant's contribution over the prior art and the commonly shared structure does not constitute a structurally distinctive portion in view of the existing prior art. Thus there is a lack of unity.

A prior art reference anticipating the claims with respect to one group would not render obvious the same claims with respect to another group. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include the invention to be examined. Applicant is advised that in addition to the election requirement a reply must include an identification all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. If claims are added after the election, applicant must indicate which are readable upon the elected invention. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

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subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.041 Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai; In re Brouwer and 35 U.S.C. §103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121

does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

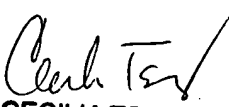
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell, Ph.D. whose telephone number is (571) 272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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D.K.O.


CECILIA TSANG
SUPERVISORY PATENT EXAMINER